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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PORTER, JR, GARY A	

ART UNIT	PAPER NUMBER
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,310	OUTRAM ET AL.	
	Examiner	Art Unit	
	GARY A. PORTER, JR	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. Specifically in regards to Claim 1 and Claim 20, Applicant claims "wherein the primary fetal heart rate component is identified through a polynomial curve fit approximation of the fetal heart rate data, and by… (ii) performing individual polynomial approximations of the fetal heart rate data." The Examiner can only find in the specification a recitation that one polynomial curve fitting is performed (*specifically individual approximations on multiple periods of time*) not a polynomial curve fitting and then another one wherein individual polynomial approximations are applied to the fetal heart rate (See page 16 line 25 – page 17, line 27 of Applicant's specification).

4. Claim 1 also contains "means for" language, which invokes 35 U.S.C. 112, sixth paragraph. The specification does not disclose adequate structure for performing the recited functions in steps a)-d) of Claim 1. Furthermore, the drawings, specifically Figure

11 does not specifically show what the "means for" doing the functions are. Only boxes are drawn that do not hold any structural weight.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim elements a)-d) of claim 1 are means plus function limitations that invoke 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. Specifically, Applicant, on page 19 of the disclosure and in Figure 11 of the drawings, merely states "means for determining a fetal heart rate (110), ...means for identifying a primary fetal heart rate component...(120), means for subtracting...(130), and means for using said residual component...(140)." The corresponding structure is not sufficiently disclosed rendering the claims indefinite.

7. Claims 2-19 are rejected under 35 U.S.C. 112, second paragraph since they are dependent on Claim 1, which is an indefinite claim.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 21 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A computer program is a "functional descriptive material" and is nonstatutory subject matter (MPEP §2106.01 [R-6]). In order to overcome this rejection, The Examiner suggests changing the claim limitation to recite, "A computer readable medium containing instructions for executing the steps of …."

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-10, 20 and 21 rejected under 35 U.S.C. 102(b) as being anticipated by Porges (US Patent 4,510,944).

11. Regarding Claim 1, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Specifically, Porges teaches a sensor 1 for detecting bioelectric potentials, specifically in regards to fetal hear rate (col. 4, lines 38-

68;col. 6, lines 55-68). Porges further teaches that the system detects a primary fetal heart rate component and then subtracts the primary fetal heart rate component from the determined fetal heart rate in order to determine a residual component (col. 6, line 64 – col. 8, line 13). The residual component is then used to provide an accurate estimate of the variances associated with heart period rhythms (col. 7, lines 65-67). Porges also teaches that the primary fetal heart rate component is identified through a polynomial curve fit approximation, wherein the fetal heart rate data is divided into periods of time and individual polynomial approximations are performed for each period (col. 6, line 64 - col. 7, line 13; col. 8, lines 23-27). Even though, Porges specifically recites the same functionality as that in Applicant's claims, none of the functionally recited elements add any structure. For instance, the only elements of Claim 1 that carry patentable weight are the "means for determining a fetal heart rate development over time", i.e. a sensor, and some form of processing circuitry that is capable of performing steps b), c), d), (i), and (ii). Therefore, the circuitry of Fig. 2a of Porges anticipates Claim 1.

12. In regards to Claim 2, the Examiner notes it has been held that the recitation that an element is "Adapted To" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.* Porges discloses after the "outliner compensator" conditions the signal, the fetal heart rate data is resampled at a rate that is twice the frequency of interest and then a polynomial curve fit approximation is

performed (col. 7, line 41 - col. 9, line 68). This teaching gives Porges the capability of performing the exact functionality as disclosed by Applicant.

13. With regards to Claims 3-5, Porges teaches that it is preferable to use a third order polynomial (col. 9, lines 50-52). However, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Porges specifically teaches that higher order polynomials can be used (Claim 4; col. 10, line 63 - col. 11, line 5) therefore giving the system the capability of using a 5^{th} or 12^{th} order polynomial without changing the structure of the invention (*specifically the circuitry in Fig. 2a of Porges*).

14. Regarding Claim 6, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44

USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Porges teaches in this case, however, that the polynomial approximation is a least squares approximation (col. 10, lines 39-41).

15. In regards to Claim 7, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In this case, Porges teaches that the fetal heart rate data is divided into 500 msec time windows (col. 8, lines 23-28; col. 9, lines 53-55) and then passed to the moving polynomial filter where they are trended (col. 10, lines 1-19). The result of the approximation is shown in Fig. 3. Since the graph is a continuous curve, it can be assumed that the approximations of the time windows align. The system as disclosed by Porges is therefore capable of performing the same function as described by Applicant.

16. With regards to Claims 8 and 9, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished

from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In his case, the system of Porges is capable of setting the time windows so that 20 consecutive heart samples can be obtained, since Porges explicitly states that as long as the sampling rate is twice the frequency of interest, any sampling rate can be chosen (col. 8, lines 20-57) thus any window of data can be set.

17. Regarding Claim 10, the Examiner notes it has been held that the recitation that an element is "Adapted To" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.* Porges teaches statistical analysis of the residual component, i.e. the variability of the heart rate, is used to determine various distress states of a fetus (col. 14, lines 11-66).

18. In regards to Claim 20, Porges teaches a sensor 1 for detecting bioelectric potentials, specifically in regards to fetal hear rate (col. 4, lines 38-68;col. 6, lines 55-68). Porges further teaches that a primary fetal heart rate component is identified and then subtracted from the determined fetal heart rate in order to determine a residual component (col. 6, line 64 – col. 8, line 13). The residual component is then used to provide an accurate estimate of the variances associated with heart period rhythms (col. 7, lines 65-67). Porges also teaches that the primary fetal heart rate component is identified through a polynomial curve fit approximation, wherein the fetal heart rate data is divided into periods of time and individual polynomial approximations are performed for each period (col. 6, line 64 - col. 7, line 13; col. 8, lines 23-27).

19. With regards to Claim 21, Porges teaches a computer readable medium with instructions on it that perform the approximations (col. 11, lines 1-48) as addressed in the rejection of Claims 1 and 20.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 11-19 rejected under 35 U.S.C. 103(a) as being unpatentable over Porges (US Patent 4,510,944) in view of Ferguson, II et al. (US Pub. 2006/0074329).

22. In regards to Claims 11-19, the Examiner notes it has been held that the recitation that an element is "Adapted To" perform a function is not a positive limitation but only requires the ability to so perform. Porges discloses performing statistical comparisons of the residual components to a control group and concluding the health of the fetus from the comparison. Porges also discloses circuitry that performs the statistical computations (*specifically variance calculations display 96, results are also evident in Fig. 4a and 4b*) in order to predict fetal distress (col. 2, lines 14-23; col. 5, lines 1-44). Porges does not disclose that distribution analysis of the 95th percentile of the fetal heart rate residual component is performed to predict fetus well-being. However, Ferguson teaches using quantitative distribution analysis to predict fetal well-being and fetal outcome (Section [0011, 0018]; Fig. 7-9). Additionally, Ferguson teaches that percentiles of interest are evaluated, i.e. 90th percentile (Section [0068]), and used

in statistical models (Section [0071]) to predict fetal condition (Section [0063]). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device in the Porges reference to include using distribution statistical analysis based on percentiles, as taught and suggested by Ferguson, for the purpose of predicting fetal abnormalities. This combination meets the claim limitations since the structure of the combination is the same as set forth in Applicant's claims. The system of the Porges and Ferguson combination is certainly capable of determining the condition of a fetus using the 95^{th} percentile since it can determine the condition of a fetus using the 90^{th} percentile.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766